

## **REMARKS**

### **I. Status of the Claims and support for the amendment.**

Claims 5–7, 15, and 24–27 are cancelled by the current amendment.

Claims 1, 8, and 9 are currently amended and new claims 28 and 29 are added.

Claims 1–4, 8, 9, 12–14, 18, 20, 23, 28, and 29 are currently pending.

Support for the amendment of claim 1 is found in the specification at page 10, lines 21–26. Support for the amendment of claim 8 is found in the specification at page 11, lines 11–14 and page 14, lines 14–24. Support for newly added claims 28 and 29 is found in claim 9 as originally filed. Applicant specifically reserves the right to any cancelled material in one or more subsequent continuation or divisional applications.

### **II. Objection under 37 C.F.R. § 1.126**

The claims are objected to as not being in compliance with 37 C.F.R. § 1.121(b). Applicant notes that claims 24 and 25 are cancelled by the instant amendments to the claims. Accordingly this rejection is moot and should be withdrawn.

### **III. Withdrawal of claim 23**

Claim 23 has been withdrawn from consideration as allegedly being drawn to a non-elected invention. In response applicant notes the withdrawal and requests rejoinder of claim 23 in accordance with *MPEP* §821.04, when claim 1 is determined to be allowable. *MPEP* §821.04 recites, in pertinent part, that: “if applicant elects claims directed to [a] product and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.”

Given that claim 23 recites the phrase “with a peptide of claim 1”, Applicant contends that it meets the require of *MPEP* §821.04 that the process claim “*depend from or otherwise include all the*

*limitations of the allowable product claim*”, namely currently amended claim 1. Accordingly, once claim 1 is found allowable, claim 23 may properly be rejoined and allowed. Moreover, claims 28 and 29, which depend from and further limit claim 23, should likewise be joined.

#### **IV. Rejection under 35 U.S.C. §112**

**A.** Claims 1–9, 12–15, 18, 20, and 24–27 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not being described in the specification sufficiently to meet the “written description” requirement. The rejection alleges that while the Specification does provide support for a “peptide comprising a sequence of *less than* 50 amino acid residues”, it does not describe a “a peptide comprising a sequence of 14–50 amino acid residues.” Applicant respectfully traverses.

As currently amended the claims no longer recite the rejected phrase. Moreover, claim 1, and all claims depending therefrom are now limited to peptides having the sequence of SEQ ID NO:4, which is fully described by the specification. Accordingly, Applicant believes that this rejection of the claims has been overcome and may now properly be withdrawn.

**B.** Claims 1–9, 12–15, 18, 20, and 24–27 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not being sufficiently described in the Specification, with respect to peptides of from 19–49 amino acids in length and because the Specification allegedly fails “to provide a representative number of species to describe the genus as broadly as claimed.” Applicant respectfully traverses.

As currently amended the claims are limited to peptides “consisting of 18 amino acids” having the sequence of SEQ ID NO:4. As noted by the Examiner, the Specification fully describes such peptides. Consequently, in view of the Amendments to the Claims, Applicant believes that this rejection has been overcome and may now properly be withdrawn.

**C.** Claims 1–9, 12–15, 18, 20, and 24–27 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which is not described in the Specification sufficiently to enable “one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or

use the invention.” Specifically, the rejection alleges that the “specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass peptides that are longer than 18 amino acid residues and that are not specifically recognized by autoimmune antibodies from patients suffering from rheumatoid arthritis (RA).” Applicant respectfully traverses.

As currently amended, the claims are limited to peptides having 18 amino acids that fit within the generic sequence of SEQ ID NO:4. Therefore, Applicant believes that the amended claims are fully enabled by the Specification. Consequently, Applicant asserts that the instant rejection of the claims under 35 U.S.C. § 112, first paragraph, as not being enabled, has been overcome and may now properly be withdrawn.

**D.** Claims 15 is rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for the use of the term “specific recognized.” In response, Applicant notes that claim 15 is cancelled by the current Amendments to the Claims. Consequently, rejection of claim 15 is moot and should be withdrawn.

**E.** Claims 25 is rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for the use of the term “small volume.” In response, Applicant notes that claim 25 is cancelled by the current Amendments to the Claims. Consequently, rejection of claim 25 is moot and should be withdrawn.

## **V. Rejection under 35 U.S.C. §103**

Claims 1–6, 8, 12–15, 18, 20, and 25 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 99/28344 in view of Jaarsveld *et al.* (*Clin. Exp. Rheum.* 17:689–697, 1999), Dyson *et al.* (*FASEB J.* 9:37–42, 1995), and alleged admissions made at page 8, lines 18–20 of the Specification. Specifically, the rejection recites that:

[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have substituted cysteine for serine in a peptide taught by

WO 99/28344 such as the peptides in claim 3 as taught by WO/28344 and to produce a cyclic peptide as taught by Jaarsveld *et al.*, WO 99/28344 and Dyson *et al.*

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to cyclize the peptide as taught by Jaarsveld and Dyson *et al.* as per Applicant's said admission in the specification, because WO 99/28344 and Dyson *et al.* teach the advantage of cyclizing the peptides for conformational stability. One of ordinary skill in the art at the time the invention was made would have been motivated to do this to prevent conformational dilution, i.e., to constrain the peptides to conformations that favor the antibody binding in such a way that they can adopt the conformational features of the original antigenic site in the intact protein and in order to use lower amounts of the peptides.

Applicant respectfully traverses.

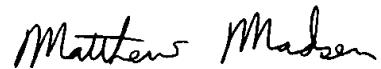
Firstly, it is noted on the record that Applicant does not concede the assertions made in the rejection. However, in view of the Amendments to the Claims, the rejections are moot. There is nothing in the cited art, when taken in combination, that renders the instantly pending claims obvious. On the contrary, SEQ ID NO:4 and SEQ ID NO:12, to which the instant claims are limited, have been specifically found to be "free of the prior art" (*see*, last line of page 11 of the instantly pending Office Action). Moreover, since SEQ ID NO:17 (*see* claims 9 and 29) is, like SEQ ID NO:12, a specific example of the more generic SEQ ID NO:4, it is believed that this claims drawn to SEQ ID NO:17 are also patentable and should be allowed with the other claims.

## **VI. Conclusion**

In view of the foregoing Remarks and Amendments to the Claims, Applicant believes that all objections to and rejections of the claims have been overcome and that the claims are in condition for immediate allowance. Accordingly, Applicant respectfully requests reconsideration of the Application and subsequent issue of a Notice of Allowance therefor.

The Examiner is invited to contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



Matthew L. Madsen  
Reg. No. 45,594  
Patent Agent for Assignee  
INNOGENETICS N.V.

HOWREY SIMON ARNOLD & WHITE, LLP  
750 Bering Drive  
Houston, Texas 77057-2198  
(713) 787-1400

Date: November 18, 2003